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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/525,681	02/23/2005	Henning Walczak	18744-0030	9513

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EXAMINER	
SCHUBERG, LAURA J	
ART UNIT	PAPER NUMBER
1657	
MAIL DATE	DELIVERY MODE
03/31/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/525,681	WALCZAK ET AL.	
	Examiner	Art Unit	
	LAURA SCHUBERG	1657	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *12 January 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-14* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-14* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

This action is responsive to papers filed 01/12/2009.

Claims 1-14 are currently pending; claims 1, 3 and 4 have been amended, claim 15 has been canceled and no claims have been added.

Claims 1-14 have been examined on the merits.

Previous Rejections

Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-14 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 recites the limitation "regardless of the disease being treated" in line 8. There is insufficient antecedent basis for this limitation in the claim as the claim does

not mention any treatment. It is unclear whether Applicant is claiming a screening method or a treatment method.

Clarification is required.

Because claims 2-14 depend from indefinite claim 1 and do not clarify the point of confusion, they must also be rejected under 35 U.S.C. 112, second paragraph.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-14 remain rejected under 35 U.S.C. 102(b) as being anticipated by Alnemri et al (US 5,786,173- from IDS).

Amended claim 1 is drawn to a method of monitoring or modulating a disease-associated activatory process, wherein the activity process comprises activation of cytokinsecretion, induction of direct cell-bound signals, or transmissions of signals regulating proliferation, differentiation, and/or senescence, the method comprising determining or influencing the amount or activity of caspase-10 or caspase-10 isoforms in a cell or an organism, which is affected by non-apoptosis signals emanating from death receptors or non-apoptosis signals from non-death receptors of the TNF receptor family regardless of the disease being treated.

Dependent claims include the signals by which the amount or activity of caspase-10 or caspase-10 isoform is affected, the type of diseases included, type of information monitored, level of determination and level of monitoring.

Alnemri et al disclose methods of monitoring and modulating disease-associated activatory processes comprising determining and/or influencing the amount or activity of Mch4 (which is the caspase 10a isoform) in a cell or organism at the nucleic acid and protein level (column 8 line 22-column 12 line 37) (claims 1, 9-14). Although it is not further specified that non-apoptosis signals are meant (and only apoptosis is discussed), cancer and autoimmune diseases are included for treatment and monitoring (column 8), and these types of diseases fall under the group of activatory processes that are also triggered by non-apoptosis signals, according to the present application (pages 5-6) and inherently include the death receptors and non-death receptors claimed by Applicant as well as receptor crosslinking (claims 2-5, 7, 8). The inclusion of systemic lupus erythematosus (column 8 line 30), while characterized as an autoimmune disease, can also be characterized as a skin inflammatory disease since it inherently includes symptoms of skin lesions as well as other inflammatory related symptoms (claim 6).

Inherency is not necessarily coterminous with the knowledge of those of ordinary skill in the art. Artisans of ordinary skill may not recognize the inherent characteristics or functioning of the prior art. However, the discovery of a previously unappreciated property of a prior art composition, or of a scientific explanation for the prior art's functioning, does not render the old composition or method patentably new to the

discoverer. The public remains free to make, use, or sell prior art compositions or processes, regardless of whether or not they understand their complete makeup or the underlying scientific principles which allow them to operate. The doctrine of anticipation by inherency, among other doctrines, enforces that basic principle.

Thus, a reference may be anticipatory if it discloses every limitation of the claimed invention either explicitly or inherently. A reference includes an inherent characteristic if that characteristic is the natural result flowing from the reference's explicitly explicated limitations.

Alnemri et al teach the physical steps of determining and influencing the amount or activity of caspase-10 or caspase-10 isoforms in a cell or an organism in specific diseases taught by Applicant to be affected by non-apoptosis signals (cancer and autoimmune diseases).

Because the Alnemri reference teaches the same physical steps as the claimed method, the teachings of Alnemri et al inherently anticipate Applicant's invention as claimed.

Response to Arguments

Applicant's arguments filed 01/12/2009 have been fully considered but they are not persuasive.

Applicant argues that the Alnemri reference does not anticipate the claims as amended. Applicant asserts a person skilled in the pertinent art would recognize the

difference between the claimed method which is directed to non-apoptosis pathways, while Alnemri's teaching focus on apoptosis pathways. Applicant asserts that Alnemri does not teach or suggest a method relying on non-apoptosis signaling.

This is not found persuasive because the Alnemri reference teaches the same physical steps as the claimed method which are "determining and influencing the amount or activity of caspase-10 or caspapse-10 isoforms". Wherein the activatory process comprises transmission of signals regulating proliferation, differentiation and/or senescence is an inherent component to the relationship of capspase-10 and diseases such hyperproliferative, inflammatory and auto-immune diseases. It is not necessary for Alnemri to recognize that caspase-10 is being affected by non-apoptosis signals in order to carrying out the monitoring and modulating method as claimed by Applicant as long as Alnemri includes embodiments wherein the diseases monitored and treated are those specified by Applicant has having these non-apoptosis signals which Alnemri does (column 7 line 50- column 8 line 5).

Therefore, the claims remain rejected as cited above.

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to LAURA SCHUBERG whose telephone number is (571)272-3347. The examiner can normally be reached on Mon-Fri 8:00-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jon Weber can be reached on 571-272-0925. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Leon B Lankford/
Primary Examiner, Art Unit 1651

Laura Schuberg